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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,628	04/27/2001	Nicolaas M. Lokhoff	P-9695	2393

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EXAMINER

BRADFORD, RODERICK D

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/03/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/844,628

Applicant(s)

LOKHOFF ET AL.

Examiner

Roderick Bradford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Response to Arguments

1. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Referring to claims 3, 11, 14 and 15, it is unknown whether applicant intends to positively recite these elements, since they have not been positively set forth ^{or} claimed. As an example in claim 3 "to interface with a stiffening member" is inferentially including the stiffening member and it is unclear if the stiffening member has been positively recited. Although the "coupling member" has been positively recited since the claim states "includes".

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3, 11, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to claim 3, "stiffening member" is vague because it is inferentially included and needs to be positively recited.

Referring to claim 11, "a sensor" is vague because it is inferentially included and needs to be positively recited.

Referring to claim 14, "respective conductor" is vague because it is inferentially included and needs to be positively recited.

Referring to claim 15, "second ring" is vague because it is inferentially included and needs to be positively recited. Also, "the at least one ring electrode" lacks antecedent basis and the claim could not be further examined based on the prior art.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 20, 31 rejected under 35 U.S.C. 102(b) as being anticipated by Termin et al. U.S. Patent No. 5,378,239.

Referring to claims 1, 20 and 31 Termin discloses an implantable device comprising: an elongated body having a proximal and distal end, the distal end including an inner lumen (Fig. 1), a helix residing within the inner lumen and adapted to be extended beyond the distal end of the elongated body (column 5, lines 28-36) and wherein at least a portion of the helix having a diameter that is larger than the diameter of the elongated body (Fig. 1).

6. Claims 1, 2, 5, 6, 9, 10, 11, 12, 19, 20, 29, 30, 31, 33 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaraczewski et al. U.S. Patent No. 5,938,694.

Referring to claims 1, 20 and 31 Jaraczewski discloses an implantable device comprising: an elongated body having a proximal and distal end, the distal end including an inner lumen (Fig. 1), a helix residing within the inner lumen and adapted to be extended beyond the distal end of the elongated body (column 5, lines 28-36) and

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wherein at least a portion of the helix having a diameter that is larger than the diameter of the elongated body (Fig. 1).

Referring to claim 2, further comprising a fixation assembly coupled to a proximal end of the helix, the fixation assembly being adapted to allow for retraction of the helix such that the helix re-assumes a compressed configuration within the inner lumen (abstract).

Referring to claim 5, wherein the diameter of the helix is extended is substantially constant (Fig. 2B).

Referring to claim 6, wherein the diameter of the helix when the helix is extended decreases towards a distal end of the helix (Fig. 2A).

Referring to claims 9 and 10, wherein the helix is formed of a super elastic material and wherein the super elastic material is a shape memory alloy (column 5, lines 19-26).

Referring to claims 11, 12, 29 and 35, wherein the elongated body is further coupled to a sensor to sense a physiological signal (column 10, lines 12-14).

Referring to claims 30 and 33 wherein the step includes expanding the helix to contact at least one wall of the vessel (column 6, lines 32-36).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 2-4, 17, 22-24 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaraczewski et al. U.S. Patent No. 5,938,694 in view of Bens et al. U.S. Patent No. 5,259,394.

Referring to claims 2, 3, 4, 17, 22-24, and 32, Jaraczewski fails to disclose further comprising at least a portion of the helix re-assumes a compressed configuration within the inner lumen, wherein the fixation assembly includes a coupling member to interface with the stiffening member, wherein the fixation assembly includes means to allow the helix to be extended and retracted by rotation of the stiffening member and wherein the fixation assembly includes a helical lumen to guide the helix during extension and retraction. However, Bens discloses further comprising at least a portion of the helix re-assumes a compressed configuration within the inner lumen (column 9, lines 47-51) as a means of more easily positioning the tube with in a body vessel, wherein the fixation assembly includes a coupling member to interface with the stiffening member (column 5, lines 6-17) as an alternate means of more easily rotating

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the helix, wherein the fixation assembly includes means to allow the helix to be extended and retracted by rotation of the stiffening member (column 6, lines 12-26 and column 9, lines 46-51) as an alternate means of more easily rotating the helix and wherein the fixation assembly includes a helical lumen to guide the helix during extension and retraction (column 3, lines 6-12) as a means to make sure that the helix is properly aligned.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Jaraczewski to include further, as taught by Bens, comprising at least a portion of the helix re-assumes a compressed configuration within the inner lumen as a means of more easily positioning the tube within a body vessel, wherein the fixation assembly includes a coupling member to interface with the stiffening member as an alternate means of more easily rotating the helix, wherein the fixation assembly includes means to allow the helix to be extended and retracted by rotation of the stiffening member as an alternate means of more easily rotating the helix and wherein the fixation assembly includes a helical lumen to guide the helix during extension and retraction (column 3, lines 6-12) as a means to make sure that the helix is properly aligned.

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jaraczewski in view of Bens et al. U.S. Patent No. 5,259,394 as applied to claim 17 above, and in further view of Doan et al. U.S. Patent No. 5,456,708.

Referring to claim 18, Jaraczewski in view of Bens fails to disclose wherein the

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helical lumen includes a seal adapted to prevent the ingress of fluids. However, Doan discloses a helical lumen includes a seal adapted to prevent the ingress of fluids (column 3, lines 14-17) as a means to stop body fluids from entering the lead body.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Jaraczewski in view of Bens to include a helical lumen includes a seal adapted to prevent the ingress of fluids, as taught by Doan, as a means to stop body fluids from entering the lead body.

11. Claims 7, 8, 14, 16, 21, 25, 28 and 34 rejected under 35 U.S.C. 103(a) as being unpatentable over Jaraczewski et al. U.S. Patent No. 5,938,694 in view of Li et al. U.S. Patent No. 5,716,390.

Referring to claims 7 and 25, Jaraczewski fails to disclose an implantable device further including a conductor to the helix whereby the helix may be used to deliver electrical stimulation. However, Li discloses an implantable device further including a conductor to the helix whereby the helix may be used to deliver electrical stimulation (column 6, lines 57-60) as a means to stimulate specific areas more efficiently.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings Jaraczewski to further include a conductor to the helix whereby the helix may be used to deliver electrical stimulation, as taught by Li, as a means to stimulate specific areas more efficiently.

Referring to claims 8 and 21, Jaraczewski fails to disclose wherein the conductor is a coiled conductor configured such that the helix may be extended and retracted by rotation imparted to a proximal end of the coiled conductor. However, Li discloses

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wherein the conductor is a coiled conductor configured such that the helix may be extended and retracted by rotation imparted to a proximal end of the coiled conductor (abstract) as a means to allow the lead to be easily repositioned to another area.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Jaraczewski to include wherein the conductor is a coiled conductor configured such that the helix may be extended and retracted by rotation imparted to a proximal end of the coiled conductor, as taught by Li, as a means to allow the lead to be easily repositioned to another area.

Referring to claims 14 and 34, Jaraczewski fails to disclose an implantable medical device further including at least one ring electrode carried on the elongated body and coupled to a respective conductor to allow for multi-polar pacing. However, Li discloses an implantable medical device further including at least one ring electrode carried on the elongated body and coupled to a respective conductor to allow for multi-polar pacing (column 1, lines 65-67 and column 2, lines 4-8) as a means to stimulate different sections of the heart.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teachings of Jaraczewski to include at least one ring electrode carried on the elongated body and coupled to a respective conductor to allow for multi-polar pacing, as taught by Li, as a means to stimulate different sections of the heart.

Referring to claims 16 and 28, Jaraczewski fails to disclose an implantable medical device further including at least one defibrillation electrode carried on the

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elongated body. However, Li discloses an implantable medical device further including at least one defibrillation electrode carried on the elongated body (column 4, lines 61-65) as a means to make the lead more efficient.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the teaching of Jaraczewski to include at least one defibrillation electrode carried on the elongated body, as taught by Li, as a means to make the lead more efficient.

12. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaraczewski et al. U.S. Patent No. 5,938,694 in view of Li et al. U.S. Patent No. 5,716,390.

Referring to claim 26, Jaraczewski in view of Li discloses the claimed invention except for wherein the elongated body further carries a ring electrode, and wherein the step includes delivering the electrical stimulation between the helix and the ring electrode.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Jaraczewski in view of Li to include delivering the electrical stimulation between the helix and the ring electrode since it was well known in the art that delivering the electrical stimulation between the helix and the ring electrode as a means to more efficiently treat the desired body tissue.

Referring to claim 27, Jaraczewski in view of Li discloses the claimed invention except for wherein the elongated body carries multiple ring electrodes, and further

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including the step of utilizing one or more predetermined ones of multiple ring electrodes to deliver electrical stimulation to one or more locations within the body.

It would have been obvious to one having ordinary skill at the time the invention was made to modify the device as taught by Jaraczewski in view of Li wherein the elongated body carries multiple ring electrodes, and further including the step of utilizing one or more predetermined ones of multiple ring electrodes to deliver electrical stimulation to one or more locations within the body since it was well known in the art to provide multiple ring electrode as a means of simultaneous provide stimulation to different body tissue.

13. Claims 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jaraczewski et al. U.S. Patent No. 5,938,694.

Referring to claim 13, Jaraczewski discloses the claimed invention except for wherein the helix lumen configured to allow blood flow to continue in an unimpeded manner at an implant site within the body.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Jaraczewski, to include the helix lumen configured to allow blood flow to continue in an unimpeded manner at an implant site within the body since it was well known in the art to include lumens that allow blood flow to continue unimpeded as means to prevent blood clots within the vessels.


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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roderick Bradford whose telephone number is (703) 305-3287. The examiner can normally be reached on Monday - Friday 7 a.m. - 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


R.B.
August 28, 2003


GEORGE R. EVANISKO
PRIMARY EXAMINER

8/28/03